

**Quality System Expert Committee (QS)
Meeting Summary**

May 14, 2018

1. Roll Call:

Paul Junio, Chair, called the meeting to order at 1pm Eastern on April 9, 2018 by teleconference. Attendance is recorded in Attachment A – there were 8 members present. Associate Members present: Eric Denman, Pepa Sassin, and Carl Kircher.

The April minutes were distributed by email. A motion was made by Michelle to accept the 4/9/18 minutes as written. The motion was seconded by Jessica and unanimously approved.

2. Louisiana Meeting

Jerry joined the call today to talk about options on how to handle the special ISO/IEC 17025 meeting in New Orleans.

He considered options on who should sit up front for the meeting. The Chairs and Vice-Chairs? Ilona suggested 3 members from NEFAP EC, LASEC, QS, LAB, NELAP AC and perhaps CSDP EC?

Meeting content could include:

- Concept of missing language in ISO/IEC 17025:2017 compared to 2005 – should missing language appear in new Standard as TNI language?
- Paul can share the summary table the committee is working with figure out where to place the language in the 2016 TNI Standard into a new format based on the organization in ISO/IEC 17025:2017.
- Chris Gunning could do a 1hour presentation on the new requirements in ISO/IEC 17025:2017. He has a presentation already that he can adjust to fit it into 1 hour. He will forward his slides to Paul/Ilona/Jerry. A2LA is looking at assessing all their labs for the additional ISO/IEC 17025/2017 changes even if the lab is only being accredited to the 2016 TNI Standard.
- Paul is doing a presentation for FSEA this month and he will forward his slides to Jerry for consideration of use at the New Orleans meeting.

The special meeting will be held on Wednesday from 1:30-5pm. Quality Systems will meet the next morning.

Jerry will get back to the committee with more information on the format and topics for the special meeting as things unfold over the next two months.

3. ISO/IEC 17025:2017 and Revision to Module 2

The committee continued their discussion on where current 2016 TNI Language might fit in the new format.

Carl asked if the language that is now in AB module can also be discussed. Paul noted that the language in question is ISO/IEC 17011 and that this causes some complications to move it into Module 2. Adding the ISO/IEC 17011 language would require labs being charged for the use of both ISO/IEC standards.

Carl stated that $\frac{3}{4}$ of the language was originally in Chapter 6 of the NELAC 2003 Standard. There shouldn't be a problem using this language. Further discussion is needed.

Paul brought up a copy of ISO/IEC 17025:2017 Standard on Webex with a start of TNI language being inserted. Ilona asked if the red text is all ISO language and the black language is TNI. Paul confirmed.

ISO/IEC 17025:2017 Section 4.1.5

TNI 4.2.8.1 was added below ISO/IEC 17025:2017 4.1.5. Paul asked if it is necessary to keep the requirement for signed integrity documentation. The group decided to leave it in.

Is "data integrity procedure document" anything more than what is required in 3? Yes. It will be left as is.

Remove "top". Leave it as just "management".

TNI Section 4.16 should be added to this section too. Same for TNI Section 5.2.7. The references to these sections in old TNI language in Section 4.2.8.1 should be removed because these sections will now be part of this section.

TNI 4.16 used the word "should". Is this still appropriate? Kathi noted it might be an issue for some ABs. Chris pointed to ISO/IEC 17025:2017 Section 4.2.2 as an out if needed, so language can be changed to "shall".

Paul had made a statement that if an AB requires that it be notified up front when an investigation is started, that would be between the lab and the AB. Matt doesn't think it should be a requirements, but just a "should". A lab can have an internal procedure that says it does not have to share anything about a data investigation until it is complete.

Chris thinks it should be a "shall" or it is not assessable. Why have it in the Standard? Should it be a note?

Shari noted that confidential can be different in different sized labs. Perhaps the language should involve stating that a limited number of people are required to be involved in the investigation process.

Kathi noted that there is a requirement that laboratory management is informed of the need for any investigation.

Iлона commented that the committee needs to decide whether it wants to include “should” in the new Standard. Or perhaps “should” should be a Note?

Kathi commented that there is text about ensuring confidentiality to make sure people are comfortable reporting these sorts of things. This makes her think it needs to be a “shall” so it sets the right tone.

Dale looks at the regulatory side and that states want you do things as quickly as possible and make the information available once it is cleared within the lab/company. He would be good with “shall” be handled in confidential manner until they are completed. He does not think states would require anything more prematurely. Dale thinks the word “shall” may help labs.

Matt agrees it should be handled in a confidential manner but that what is being discussed may be too prescriptive for the Standard. It is up to the lab to decide on how to handle the information once it has been investigated. It should be “should”.

Another part of the Standard requires that management have a procedure to maintain confidentiality. Making the language being discussed a “should” could risk this other requirement. Perhaps the “shall” should be consistent.

Kathi expressed concerns about whether someone can force the lab to make the information public? Is there some value in protecting the lab if someone wants to look at it and shouldn't have access?

Iлона commented that perhaps we are getting into too much detail. The goal is to state the end result and perhaps the labs should have some flexibility on how to meet those end goals.

Kathi is worried that taking language out may cause pushback from the community.

Paul asked who would like language to be “should” and who would like to see “shall”. There was overwhelming support for “shall”. The language will be updated.

Paul moved on to language from TNI Section 5.2.7 – Data Integrity Training. He reviewed the current language with the committee. Kathi commented that the last sentence is strictly information and should be a Note.

ISO/IEC 17025:2017 Section 5.6

Paul inserted 2016 TNI Standard Sections 4.1.7.1 and 4.1.7.2.

A sentence would need to be added before 4.1.7.1 and 4.1.7.2 that states there shall be a quality manager and technical manager. Paul added the language as 5.2.1 and 5.2.2. Perhaps this is a good spot to add the lab key staff. The language about limited staff and the combination of quality manager and technical manager roles needs to be added. It was added to Section 5.2.2 (new section noted above).

2016 TNI Standard Section 4.1.7.2 will be the starting point next month.

4. Action Items

A summary of action items can be found in Attachment B.

5. New Business

None.

6. Next Meeting and Close

The next meeting is planned for June 11, 2018 by teleconference from 1-3pm. Ilona will send a Webex invitation the morning of the meeting.

A summary of action items and backburner/reminder items can be found in Attachment B and C.

Paul adjourned the meeting at 2:25pm Eastern. (Michelle - motion Dale – second, unanimous approval).

Attachment A

**Participants
Quality Systems Expert Committee (QS)**

Member	Organization	Expiration	Representation	Email
Paul Junio (Chair) Present	Northern Lake Service	2019	Laboratory	paulj@nlslab.com
Jessica Jensen (Vice Chair) Present	Meridian Analytical Labs	2021	Laboratory	jessica.j@meridiantesting.com
Kristin Brown Present	Utah DOH	2021	Accrediting Body	kristinbrown@utah.gov
Lizbeth Garcia Present	Oregon Dept. of Environmental Quality	2019*	Accrediting Body	LIZBETH.GARCIA@dhsosha.state.or.us
Kathi Gumpfer Present	ChemVal Consulting	2021*	Other	kgumpfer@chemval.com
Chris Gunning Present	A2LA	2021	Accrediting Body	cgunning@a2la.org
Earl Hansen Absent	Retired	2021*	Laboratory	papaearl41@hotmail.com
Sara Hoffman Absent	Kansas DHE	2019*	Accrediting Body	sara.hoffman@ks.gov
Jacob Oaxaca Absent	California State Water Board	2019*	Accrediting Body	Jacob.Oaxaca@Waterboards.ca.gov
Shari Pfalmer Present	ESC Lab Sciences	2021	Laboratory	spfalmer@esclabsciences.com
Dale Piechocki Present	Eurofins Eaton Analytical	2020	Laboratory	DalePiechocki@eurofinsUS.com
William Ray Absent	William Ray Consulting	2020*	Other	Bill_Ray@williamrayllc.com
Matt Sowards Present	ACZ Laboratories, Inc.	2020	Laboratory	MattS@acz.com
Michelle Wade Present	Wade Consulting	2021*	Other	michelle@michellefromks.com
Alyssa Wingard Present	NAVSEA LQAO	2021*	Other	alyssa.wingard@navy.mil
Ilona Taunton (Program Administrator) Present	The NELAC Institute	n/a	(828)712-9242	Ilona.taunton@nelac-institute.org

Attachment B

Action Items – QS Expert Committee

	Action Item	Who	Expected Completion	Actual Completion
25	Follow-up with Bob Wyeth and Jerry Parr about experience vs. course hours for Technical Directors.	Paul	TBD	
26	Provide in writing, thoughts regarding options for Technical Director approval.	Robin	TBD	
38	Continue SIR 246 and 296 discussions.	All	TBD	
40	Get PT root cause analysis example from Scott Hoatson.	Paul	8/31/17	
45	Review Ch 1 Application section for the use of “shall” and “may”. Are uses correct?	Paul, Sara	11/20/17	
51	Send example of Shari’s report to NELAP AC to confirm format of listing all certifications without logo’s is an acceptable process to report certifications for work being done.	Shari Paul	5/11/18	
52	Send copy of Chris and Paul’s presentation to Jerry.	Paul/Ilona	5/15/18	

